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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,714	01/14/2000	YECHIEL SHAI	SHAI=2	4669

1444 7590 04/25/2005  
BROWDY AND NEIMARK, P.L.L.C.  
624 NINTH STREET, NW  
SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER
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LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/367,714

Applicant(s)

SHAI ET AL.

Examiner

David Lukton

Art Unit

1653

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 06 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see accompanying sheets. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: none.  
Claim(s) objected to: none.  
Claim(s) rejected: 9-11, 13, 38 and 40-49.  
Claim(s) withdrawn from consideration: 21 and 50-52.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached sheets.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

Advisory Action

For example, the response (filed 4/6/05) directs the amendment of claims 40, 41 and 47 to recite that the peptide must have 6-12 amino acids, and that glycine and tyrosine are excluded. This amendment would require new consideration and search.

Claims 9-11, 13, 21, 38, 40-52 remain pending. Claims 21 and 50-52 remain withdrawn from consideration. Applicants arguments filed 4/6/05 are found not persuasive; the previously imposed rejections are maintained.



The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11, 13, 38, 40-49 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification asserts that the claimed peptides are effective to cause lysis of

pathogenic cells. The question was raised in the previous Office action as to the basis for this assertion. In response, applicants have pointed to page 43, line 26+, where there are various assertions. However, assertions alone do not constitute evidence. Applicants have also pointed to figure 14. Figure 14C does tend to suggest that the peptide designated [D]-L<sup>3,4,8,10</sup>-K<sub>4</sub>-L<sub>8</sub> is effective to lyse *E. coli*. However, this property does not appear to be shared by other members of the genus. For example, the peptide designated [D]-L<sup>3,4,8,10</sup>-K<sub>5</sub>-L<sub>7</sub> appears to be ineffective, as does the peptide designated [D]-L<sup>3,4,8,10</sup>-K<sub>7</sub>-L<sub>5</sub>. Thus, the specification provides no guidance as to which of the peptides will lyse *E. coli* and which will not. Furthermore, it could well be the case that [D]-L<sup>3,4,8,10</sup>-K<sub>4</sub>-L<sub>8</sub> lyses red blood cells (as determined by electron microscopy) under the same conditions that it lyses the *E. coli*, in which case this peptide would fall outside the scope of the claimed invention.

It may be the case that, at some point in the future, applicants will be able to show that most of the peptides within the genus will cause lysis of *E. coli*, as determined by electron microscopy, and at the same time, that the peptides of the genus will not lyse RBC's under the same conditions. However, as matters currently stand, the rejection is maintained.

. . . . .

In addition to the foregoing, all of the prior art rejections that were imposed at the time of the previous Office action (mailed 12/6/04) are maintained. Applicants have traversed these rejections as if the amendment (filed 4/6/05) will be entered. Since the amendment

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will not be entered, maintaining the rejections remains justified.

✦

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800